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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,256	01/20/2004	Emmanuel Conseiller	ST98033	6927

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,256	CONSEILLER ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-97* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 32, drawn to polypeptides comprising all or part of SEQ ID NO:9 or SEQ ID NO:16, classified in class 530, subclass 324.

II. Claims 33 and 35, drawn to polypeptides comprising all or part of SEQ ID NO:31 or SEQ ID NO:22, classified in class 530, subclass 330.

III. Claim 34, drawn to polypeptides comprising all or part of SEQ ID NO:33, classified in class 530, subclass 350.

IV. Claims 37, 41, 43, 44, 47, 48, 52, 53, 57, 58, 62, 63, and 67, drawn to nucleic acids encoding SEQ ID NO:9 or SEQ ID NO:16 or comprising all or part of SEQ ID NO:15, and vectors and host cells containing said nucleic acids, classified in class 536, subclass 23.1.

V. Claims 38, 40, 41, 43-47, 49, 51, 52, 54, 56, 57, 59, 61, 62, 64, 66, and 67, drawn to nucleic acids encoding SEQ ID NO:31 or SEQ ID NO:22 or comprising all or part of SEQ ID NO:30 or SEQ ID NO:21, and vectors and host cells containing said nucleic acids, classified in class 536, subclass 23.4.

VI. Claims 39, 42, 47, 50, 52, 55, 57, 60, 62, 65, and 67 drawn to nucleic acids encoding SEQ ID NO:33 or comprising all or part of SEQ ID NO:32, and vectors and host cells containing said nucleic acids, classified in class 536, subclass 23.5.

VII. Claim 68, drawn to method of making a polypeptide of SEQ ID NO:9 or SEQ ID NO:16, classified in class 435, subclass 69.1.

VIII. Claims 69 and 71, drawn to method of making a polypeptide of SEQ ID NO:31 or SEQ ID NO:22, classified in class 435, subclass 71.1.

IX. Claim 70, drawn to method of making a polypeptide of SEQ ID NO:33, classified in class 435, subclass 71.2.

X. Claims 72, 74-76 and 96, drawn to the antisense of SEQ ID NO:15, classified in class 514, subclass 44.

XI. Claims 72, 74-76 and 96, drawn to the antisense of SEQ ID NO:21 or SEQ ID NO:30, classified in class 536, subclass 24.1.

XII. Claims 73, 76 and 96, drawn to the antisense of SEQ ID NO:32, classified in class 536, subclass 24.5.

XIII. Claims 77 and 81, drawn to nucleic acid probes capable of hybridizing with SEQ ID NO:15, classified in class 536, subclass 22.1.

XIV. Claims 78, 80, and 81, drawn to nucleic acid probes capable of hybridizing with SEQ ID NO:21 or SEQ ID NO:30, classified in class 536, subclass 24.3.

XV. Claims 79 and 81, drawn to nucleic acid probes capable of hybridizing with SEQ ID NO:32, classified in class 536, subclass 24.31.

XVI. Claims 82, 83 and 97, drawn to an antibody directed against SEQ ID NO:9 or SEQ ID NO:16, classified in class 530, subclass 387.1.

XVII. Claims 82, 83 and 97, drawn to an antibody directed against SEQ ID NO:31 or SEQ ID NO:22, classified in class 530, subclass 387.3.

XVIII. Claims 82, 83 and 97, drawn to an antibody directed against SEQ ID NO:33, classified in class 530, subclass 388.1.

XIX. Claim 83, drawn to an oncogenic p53 antibody capable of preventing the interaction between oncogenic p53 and a polypeptide capable of interacting specifically with oncogenic forms of p53, classified in class 530, subclass 387.7.

XX. Claim 85, drawn to a method for detecting a compound capable of specific binding to SEQ ID NO:9 or SEQ ID NO:16, classified in class 435, subclass 7.1.

XXI. Claim 85, drawn to a method for detecting a compound capable of specific binding to SEQ ID NO:31 or SEQ ID NO:22, classified in class 435, subclass 7.2.

XXII. Claim 85, drawn to a method for detecting a compound capable of specific binding to SEQ ID NO:33, classified in class 435, subclass 7.23.

XXIII. Claim 87, drawn to a method for detecting a compound capable of modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:9 or SEQ ID NO:16, classified in class 435, subclass 7.8.

XXIV. Claim 87, drawn to a method for detecting a compound capable of modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:31 or SEQ ID NO:22, classified in class 435, subclass 7.9.

XXV. Claim 87, drawn to a method for detecting a compound capable of modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:33, classified in class 435, subclass 8

XXVI. Claims 89 and 92, drawn to a compound capable of modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:9 or SEQ ID NO:16, classified in class 530, subclass 300.

XXVII. Claims 89 and 92, drawn to a compound capable of modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:31 or SEQ ID NO:22, classified in class 530, subclass 300.

XXVIII. Claims 89 and 92, drawn to a compound capable of modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:33, classified in class 530, subclass 300.

XXIX. Claim 90, drawn to a compound capable of specific binding to SEQ ID NO:9 or SEQ ID NO:16, classified in class 530, subclass 324.

XXX. Claim 90, drawn to a compound capable of specific binding to SEQ ID NO:31 or SEQ ID NO:22, classified in class 530, subclass 326.

XXXI. Claim 90, drawn to a compound capable of specific binding to SEQ ID NO:33, classified in class 530, subclass 330.

XXXII. Claim 94, drawn to a method of administering a compound capable modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:9 or SEQ ID NO:16 to a cell, classified in class 514, subclass 2.

XXXIII. Claim 94, drawn to a method of administering a compound capable modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:31 or SEQ ID NO:22 to a cell, classified in class 514, subclass 4.

XXXIV. Claim 94, drawn to a method of administering a compound capable modulating or inhibiting the interaction between oncogenic p53 and SEQ ID NO:33 to a cell, classified in class 514, subclass 6.

XXV. Claim 95, drawn to a method of determining a structural component of SEQ ID NO:9 or SEQ ID NO:16 that is responsible for binding to an oncogenic form of p53, classified in class 435, subclass 7.5.

XXXVI. Claim 95, drawn to a method of determining a structural component of SEQ ID NO:9 or SEQ ID NO:16 that is responsible for binding to an oncogenic form of p53, classified in class 435, subclass 7.6.

XXXVII. Claim 95, drawn to a method of determining a structural component of SEQ ID NO:33 that is responsible for binding to an oncogenic form of p53, classified in class 435, subclass 7.7.

2. Claim 31 links inventions of Groups I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 31. Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is

presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claim 36 links inventions of Groups IV-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 36. Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312

Claim 84 links inventions of Groups XX-XXII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 84. Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claim 86 links inventions of Groups XXIII-XXV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 86. Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Claims 88 and 91 link inventions of Groups XXVI-XXVIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 88 and 91. Upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups (I-III), (IV-VI), (X-XII), (XIII-XV), (XVI-XIX), (XXVI-XXVIII) and (XXXV-XXXVII) represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The polypeptides of Groups (I-III), the polynucleotides of Groups (IV-VI), the antisense polynucleotides of Groups (X-XII), the nucleic probes of Groups (XIII-XV), the antibodies of Groups (XVI-XIX), the compounds of Groups (XXVI-XXVIII), and the compounds of Groups (XXXV-XXXVII) are all structurally and chemically different from each other. A polynucleotide's structure is comprised of linear, consecutive nucleotides, an antisense polynucleotide's structure is comprised of linear, consecutive nucleotides that are complimentary to a polynucleotide, a nucleic acid probe is comprised of linear, consecutive nucleotides that hybridize to a polynucleotide, a polypeptides's structure is comprised of linear, consecutive amino acids that fold into a specific three-dimensional structure, and while both polypeptides and antibodies are structurally related by virtue of their contiguous

sequence of amino acids, they are distinct structures based on their three-dimensional structures, wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. A compound's structure is undefined, but includes, in part, small molecules, peptides and nucleic acids. In the instant case, the polynucleotides of Groups (IV-VI), the antisense polynucleotides of Groups (X-XII), and the nucleic probes of Groups (XIII-XV) are not disclosed as capable of being used one for the other. Additionally, the compounds of Groups (XXVI-XXVIII), and the compounds of Groups (XXXV-XXXVII) are also not disclosed as capable of being used one for the other. The polypeptide is made by translation of mRNA, the polynucleotides are made by nucleic acid synthesis, the antibody is raised by immunization and compounds can be made by these and other means including chemical synthesis. Furthermore, the polypeptide can be used for the methods of treatment, the polynucleotide can be used for hybridization screening, the antibody can be used to purify the antigen, and the compounds could be used in chemical synthesis, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups (I-III), (IV-VI), (X-XII), (XIII-XV), (XVI-XIX), (XXVI-XXVIII) and (XXXV-XXXVII) are patentably distinct.

Inventions of Groups (I, IV, X, XIII, XVI, XXVI, and XXIX), (II, V, XI, XIV, XVII, XXVII, and XXX), (III, VI, XII, XV, XVII, XXVIII, and XXXI) and XIX represent separate and distinct products, which are made by materially different methods, and are used in materially different methods. The inventions of Groups (I, IV, X, XIII, XVI, XXVI, and

XXIX), (II, V, XI, XIV, XVII, XXVII, and XXX), (III, VI, XII, XV, XVII, XXVIII, and XXXI) and XIX are all distinct from each other as they are directed to unique polypeptides that differ structurally and functionally. For example, Groups (I, IV, X, XIII, XVI, XXVI, and XXIX) are directed to SEQ ID NO:16 or its fragments, Groups (II, V, XI, XIV, XVII, XXVII, and XXX) are directed to SEQ ID NO:22 or its fragments, Groups (III, VI, XII, XV, XVII, XXVIII, and XXXI) are directed to SEQ ID NO:33 or its fragments and Group XIX is directed to oncogenic p53. These proteins are distinct in that they have different amino acid sequences giving them distinct structures and functions. Thus, the nucleic acids that encode them, the antisense molecules that inhibit their expression, the nucleic acid probes that hybridize with them, the antibodies that target them, the compounds that specifically bind them and the compounds that modulate or inhibit their interaction with oncogenic p53 are all structurally and functionally distinct in their own right. Therefore art on one would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups (I, IV, X, XIII, XVI, XXVI, and XXIX), (II, V, XI, XIV, XVII, XXVII, and XXX), (III, VI, XII, XV, XVII, XXVIII, and XXXI) and XIX are patentably distinct.

The methods of inventions of Groups VII-IX, XX-XXII, XXIII-XXV, XXXII-XXXIV and XXXV-XXXVII differ in the method objectives, method steps and parameters and in the reagents used. The invention of Groups VII, VIII and IX recite a method of producing a recombinant polypeptide or polypeptide fragment of SEQ ID NO:16, SEQ ID NO:22, or SEQ ID NO:33, respectively. The invention of Groups XX, XXI and XXII

recite a method of detecting novel compounds that bind a polypeptide or polypeptide fragment of SEQ ID NO:16, SEQ ID NO:22, or SEQ ID NO:33, respectively. The invention of Groups XXIII, XXIV and XXV recite a method of detecting novel compounds that modulate or inhibit the interaction with oncogenic p53 and a polypeptide or polypeptide fragment of SEQ ID NO:16, SEQ ID NO:22, or SEQ ID NO:33, respectively. The invention of Groups XXXII, XXXIII and XXXIV recite a method of administering a compound capable modulating or inhibiting the interaction between oncogenic p53 and a polypeptide or polypeptide fragment of SEQ ID NO:16, SEQ ID NO:22, or SEQ ID NO:33, respectively, to a cell. The invention of Groups XXXV, XXXVI and XXXVII recite a method of determining a structural component of SEQ ID NO:16, SEQ ID NO:22, or SEQ ID NO:33, respectively, that is responsible for binding to an oncogenic form of p53. Therefore, the methods of inventions of Groups VII-IX, XX-XXII, XXIII-XXV, XXXII-XXXIV and XXXV-XXXVII differ in the method objectives, method steps, parameters and reagents used. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups VII-IX, XX-XXII, XXIII-XXV, XXXII-XXXIV and XXXV-XXXVII are separate and distinct in having different method objectives, method steps, parameters, reagents used and different endpoints and are patentably distinct.

Inventions of Groups VII-IX and Groups I-III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially

different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptides and polypetide fragments of Groups I-III could be made by a cell-free system method, such as the *in vitro* rabbit reticulate lysate cell-free translation system, which is materially different process than the cell-dependent system method claimed in Groups VII-IX and is therefore distinct.

Inventions of Groups XXVI-XXVIII and Groups XXXII-XXXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compounds of Groups XXVI-XXVIII could be used in a materially different process such as the starting compound in a chemical synthesis process, which differ in the method objectives, method steps and parameters from the method of administering the compound to a cell of Groups XXXII-XXXIV and are therefore distinct.

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy

571-272-9935

David Blanchard
AU 1643